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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,267	08/16/2001	Clinton C.S. Chapple	N1422-005	1973
32905 7590 03/24/2004 JONDLE & ASSOCIATES P.C. 9085 EAST MINERAL CIRCLE SUITE 200 CENTENNIAL, CO 80112			EXAMINER KALLIS, RUSSELL	
			ART UNIT 1638	PAPER NUMBER

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8/19

Office Action Summary

Application No.

09/931,267

Applicant(s)

CHAPPLE ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 2-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claims 1-26 are pending and Claims 1 and 8 drawn to SEQ ID NO: 4 or 6 are examined.

Claims 2-7 and 9-26 drawn to non-elected subject material are withdrawn from consideration.

The rejection of Claims 1 and 8 under 35 U.S.C. 102(b) as anticipated by Chang is withdrawn in view of Applicant's amendments.

The rejection of Claims 1 and 8 under 35 U.S.C. 112, 2nd paragraph, is withdrawn in view of Applicant's arguments and amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Applicant broadly claims a method of altering the content or composition of lignin in a plant by transformation with an isolated DNA encoding a protein having at least 84% sequence identity with the amino acid sequence of SEQ ID NO: 4 or 6 or encoding a polypeptide orthologous to the *Arabidopsis* C3H polypeptide wherein said DNA or a fragment thereof is capable of altering lignin content or composition in a plant.

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Applicant describes an isolated DNA from *Arabidopsis* of SEQ ID NO: 1 encoding SEQ ID NO: 4 and 6; and the *ref8* mutant of SEQ ID NO: 1, set forth in SEQ ID NO: 2 encoding SEQ ID NO: 5 and 7 that have.

Applicant does not describe an isolated nucleic acid sequence or fragments thereof encoding a polypeptide having at least 84% sequence identity to SEQ ID NO: 4, or any other polypeptide orthologous to the *Arabidopsis* C3H of SEQ ID NO: 4.

Applicant asserts that words are sufficient to show possession of the claimed invention (response page 10-12) and that combined with the recitation of functional activity the description set forth in the specification shows possession of the claimed invention (response pages 12-13). The words that describe the invention must describe a representative number of sequences that have the claimed activity or describe conserved structural regions that are correlated with the functional activity common to all members of the claimed genus of sequences. Clearly Applicant's specification does not recite in words, structures, figures, diagrams, or formulas a representative number of sequences or the essential structural elements that would define a genus required to show possession of the invention as broadly claimed.

Claims 1 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The added claimed material which is not supported by the original disclosure is as follows: Newly amended Claim 1 recites 84% sequence identity to the coding sequence of SEQ

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ID NO: 4 while the specification only supports identity for the polypeptide sequence of SEQ ID NO: 4 of 80%, 90% and 95%. Claim 1 recites an isolated DNA in sense or antisense orientation or a fragment thereof, while the specification only supports portions of antisense and is silent with respect to sense fragments. Applicant is invited to point to the page and line number in the specification where support can be found. Absent of such support, Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of decreasing using SEQ ID NO: 4 and 6, does not reasonably provide enablement for a full scope of altering using any fragment or sequences having less than 100% sequence identity to SEQ ID NO: 4 and 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant broadly claims a method of altering the content and composition of lignin in a plant by transformation with an isolated DNA encoding a protein having at least 84% sequence identity with the amino acid sequence of SEQ ID NO: 4 or 6 or with a DNA encoding a polypeptide orthologous to the *Arabidopsis* C3H polypeptide wherein said DNA or a fragment thereof is capable of altering the lignin content or composition in a plant.

Applicant teaches an isolated DNA from *Arabidopsis* of SEQ ID NO: 1 encoding SEQ ID NO: 4 and 6; and the *ref8* mutant of SEQ ID NO: 1, set forth in SEQ ID NO: 2 encoding SEQ ID NO: 5 and 7.

Applicant does not teach plants transformed with SEQ ID NO: 1, encoding SEQ ID NO: 4 and 6, in either sense or antisense orientation having altered content or composition of lignin.

Applicant has provided no working examples of plants transformed with any fragments of SEQ ID NO: 4 or 6; or any sequences that have less than 100% sequence identity to SEQ ID NO: 4 or 6; or any fragments that would cover any number of or combinations of unspecified additions, substitutions, and deletions thereof while retaining C3H activity. The state of the art does not recognize methods of altering lignin biosynthesis using non-exemplified fragments polynucleotide sequence encoding a C3H enzyme and the specification does not teach which regions of the sequences encoding wither SEQ ID NO: 4 or 6 would tolerate substitutions, additions or deletions to make a polypeptide having less than 100% sequence identity to SEQ ID NO: 4 or 6 and still retain C3H activity or how to make polynucleotide fragments or polypeptide fragments that would either decrease or increase lignin biosynthesis or alter lignin composition. Further, Applicant should note that without an expression step, the method can only be used to decrease lignin and is not enabled for a method "of altering" as commensurate in scope with the claims.

Altering lignin content or lignin structure by transforming plants with genes known to be involved in lignin biosynthesis produces unpredictable results including plants whose development and morphology have been altered. Hu *et al.* (Nature Biotechnology, 1999, 17:808-812) teach that efforts to reduce tree lignin content by down regulating genes encoding

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caffeate O-methyltransferase or cinnamyl alcohol dehydrogenase did not succeed (page 808, left column, 2nd paragraph). They continue by stating that these results are in agreement with other researchers who tried to reduce lignin content in tobacco.

Moreover, unpredictability in altering lignin in plants is made evident when the pathways and intermediates of the metabolic process in question are not clearly delineated and the models for lignin biosynthesis are still open to a wide range of possible interpretations such that orthologs or enzymes having limited sequence identity to the enzyme in question, or non-exemplified fragments, would not fulfill the expectations predicated by the specification and would require undue experimentation to eliminate non-functional embodiments of the invention given the lack of guidance available to one of skill in the art (Franke R. *et al.*, Plant Journal 2002, Vol. 30, No. 1; pages 33-45; on page 33 2nd column, lines 1-14; page 34 2nd column, lines 12-18; page 40 2nd column, discussion 2nd paragraph; and page 41 1st column, last paragraph to end of discussion). Given the unpredictability in the art as to which substitutions of an isolated polynucleotide encoding a polypeptide having 75% sequence identity to SEQ ID NO: 4 or a fragment thereof; or an isolated DNA encoding a peptide orthologous to the *Arabidopsis* C3H polypeptide or a fragment thereof would be tolerated; the breadth of the claims encompassing an isolated polynucleotide encoding a polypeptide having at least 75% sequence identity to SEQ ID NO: 4, an isolated DNA encoding a peptide orthologous to the *Arabidopsis* C3H polypeptide, or fragments thereof, wherein DNA sequences when expressed in a plant alter lignin content or composition; the lack of guidance in the examples of the specification or in the prior art as to which substitutions or deletions would best serve the invention or which variants of an isolated polynucleotide encoding SEQ ID NO: 4 (*Arabidopsis* C3H) would best retain activity in a plant;

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although one of skill in the art can readily make nucleotide substitutions to a polynucleotide sequence or create fragments one would not know based upon Applicant's disclosure which embodiments would be inoperable and predictably eliminated, and thus undue trial and error experimentation would be needed by one skilled in the art to make and clone a multitude of non-exemplified variants of encoding SEQ ID NO: 4 or an *Arabidopsis* ortholog and would require one of skill in the art to test in a myriad of non-exemplified plants for enhanced expression of a polynucleotide coding sequence to alter the phenotype in a multitude of non-exemplified transformed plant species. Therefore, the invention is not enabled for the scope commensurate with the claims.

Applicant asserts that the Hu reference at best demonstrates that some experimentation might be required and that the references cited in Hu are not contemporary to the instant application (response page 14). Applicant further asserts that even if the Franke reference is correct in proposing that the pathways and models for lignin biosynthesis are not clearly delineated and are open to interpretation, the experimentation required to make or use the invention is not undue because determining whether a given sequence would alter lignin content or composition in a transformed plant is provided for in the specification (response page 14). Given that applicant is claiming a broad range of non-exemplified sequences (i.e. C3H orthologs and sequences having less than 100% sequence identity to SEQ ID NO: 4 and 6), and non-exemplified fragments for transformation into any plant species, wherein there is no guidance provided for either increasing or decreasing levels of expression of a *ref8* gene using an C3H (*ref8*) ortholog when transformed into any plant species would require screening a myriad of cDNA libraries using a heterologous probe, testing for C3H activity, and transforming into a

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multitude of non-exemplified plants to test for the ability to alter lignin content or composition in a multitude of species. Thus, in view of the lack of guidance and working examples in the specification the amount of trial and error experimentation is undue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Bloksberg L. *et al.*, U.S. Patent 5,850,020 issued December 15, 1998.

The reference teaches a method of altering the content or composition of lignin in a plant by transformation using an isolated DNA encoding a polypeptide ortholog of the *Arabidopsis* C3H polypeptide, when expressed in a plant, either in sense or antisense orientation, is capable of altering lignin content or composition; and the plant thereof (see Abstract, column 2 lines 1-30, column 4 lines 32-49, and column 7 line 36 to column 8 line 46). Thus the reference teaches all the limitations of the Claims.

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Siminszky B. *et al.* PNAS, February 1999, Vol. 96, pp. 1750-1755.

The reference teaches a polypeptide sequence having 85.5% sequence identity to SEQ ID NO: 6, and regenerated plants transformed therewith, inherently teaches a method of altering the

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content or composition of lignin in a plant (see Abstract and page 1750 column 2, lines 24-35; and attached sequence report). Thus the reference teaches all the limitations of the Claims.

All Claims are rejected.

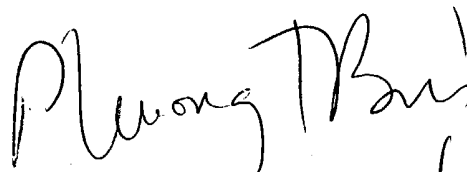
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
March 11, 2004



PHUONG T. BUI
PRIMARY EXAMINER

3/22/04